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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,484	03/16/2006	Yoshinori Kosugi	20078.0027USWO	7353

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
07/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,484	KOSUGI ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,17 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,17 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed May 6, 2010 is acknowledged and has been entered. Claims 30 and 31 have been amended. Claim 32 has been added. Accordingly, claims 15, 17, and 30-32 are pending and are under examination.

Withdrawn Rejections / Objections

2. All rejections or objections not reiterated herein, have been withdrawn.

3. In light of Applicant's amendment, the rejection of claim 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is hereby, withdrawn.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

In this case, claim 30 as amended recites "A method of diagnosing a condition in a subject" … "the condition being (1) endometriosis, (2) a disease caused by endometriosis" which is not supported or adequately described in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15, 17, and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is indefinite in lacking antecedent basis in the specification for the recitation of "a condition in a subject ... being (1) endometriosis, (2) a disease caused by endometriosis."

Claim 30 is vague and indefinite in reciting, "a condition" because the term "condition" is a subjective term that lacks a comparative basis for defining its metes and bounds. It is specifically unclear what Applicant intends to encompass in the term "condition" as used in the claim and how it pertains to endometriosis, since endometriosis appears to be a disease, rather than a condition of a disease. Does Applicant simply intend "a disease in a subject … the disease being endometriosis?"

Claim 30 is also confusing in reciting "A method of diagnosing a condition in a subject" and "the condition being (1) endometriosis, (2) a disease caused by endometriosis…" and "the disease caused by endometriosis being dysmenorrhea, infertility, or adenomyosis uteri" because dysmenorrhea, infertility, or adenomyosis uteri appear to be conditions, rather than diseases. As an example, it is unclear how "infertility" and " dysmenorrhea" are characterized as disease rather than condition, since they appear to be conditions caused by the occurrence of endometriosis.

Claim 30 is also ambiguous in reciting, "determining if the subject has the condition based on the comparison" because it is unclear as to whether the recitation of

the term "determining" intends an actual active positive method step in the claimed method because it appears to recite a mental step instead.

Claim 30 is also indefinite in reciting, “indicates … (1) endometriosis, (2) a disease caused by endometriosis (dysmenorrhea, infertility, adenomyosis uteri), or (3) a risk for endometriosis” because it fails to clearly define how “endometriosis”, “a disease caused by endometriosis” or “risk for endometriosis” and also “dysmenorrhea, infertility, adenomyosis uteri” should be differentially and individually identified and diagnosed between each other simply using HRF protein as the sole molecular marker.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 15, 17, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any literal support for the recitation of "a condition in a subject … being (1) endometriosis, (2) a disease caused by endometriosis", (3) a risk for endometriosis or disease caused by endometriosis…”. Applicant’s disclosure provides generally in [0063] diseases related

to endometriosis means endometriosis and dysmenorrheal, infertility, adenomyosis uteri" but fails to provide literal support for such recitation. Paragraph [0070] makes reference to "conditions" of transplanted colonies of HRF-overexpressing cells as related to their level of growth. The recitation of "a condition in a subject ... being endometriosis ..." appears to encompass limitations that are not described in the specification so as to provide to one skilled in the art the metes and bounds defined by the claimed invention. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 15, 17, and 30-32 stand rejected under 35 U.S.C. 102(b) as being inherently anticipated by Hochstrasser et al. (WO 94/12881)).

Hochstrasser et al. teach an immunological method to detect a marker protein designated as Translationally Controlled Tumor Protein p21 (TCTPp21) present in growing cells (Abstract). Immunological methods include fluorescent immunoassays and ELISA. Increase of this marker protein in growing cells provides indication of active cell growth which in cancer conditions, i.e. ovarian cancer cells and cervical cancer

cells, is unregulated. Hochstrasser et al. specifically teach generating antibodies specific to TCTPp21 and using these anti-TCTPp21 antibodies to detect TCTPp21 present in the cells. TCTPp21 may also be expected in lymph nodes or body fluid of patients (p. 1 line 9 to p. 2, line 5; and p. 4, lines 24-34). Where cell tissues are obtained, Hochstrasser et al. teach lysing the cells so as to release or expose the TCTPp21 protein and use the lysate in immunoassay to detect the TCTPp21 protein (p. 4, line 35 to p. 5, line 4 and p. 6, lines 14-19). The sample is contacted with a first anti-TCTPp21 antibody that is immobilized to a solid support (ELISA plate) and that binds to an epitope of the TCTPp21 protein. After the plate containing the sample is incubated and then washed, the sample is further contacted to a second anti-TCTPp21 protein antibody that is conjugated to a fluorescent or enzyme label and that binds to another epitope on the TCTPp21 protein to label the protein bound to the solid support. The labeled resulting complex on the support is measured so as to obtain a concentration of the TCTPp21 protein and then compared to normal TCTPp21 protein control levels (p. 12, Example 2). The first antibody and the second antibody may be polyclonal or monoclonal and are generated from TCTPp21 immunogen or peptide fragment thereof which comprises a peptide having a sequence of 5-20 amino acid residues (16 AA residues: GKLEEQRPERVKPFMT) within 1-41 amino acid positions of TCTPp21 protein.

In as far as the histamine-releasing factor or HRF protein (SEQ ID No. 2) and antibodies specific thereto recited in claims 15 and 17, the amino acid residues of TCTP21 immunogen as taught by Hochstrasser et al. in 1-41 AA positions is 100%

homologous to the amino acid residues within 90 to 130 AA positions of SEQ ID No. 2 (p. 6, lines 7-13).

As to claim 32 which recites that the peptide containing a sequence of 5 to 20 amino acid residues … is at positions 101 to 116 of SEQ ID NO: 2, the fact that the TCTP21 immunogen taught by Hochstrasser has 100% homology to that of the amino acid residues of SEQ ID NO. 2, is an indication that the same peptide is contained in the same sequence and positions as that recited in the claimed invention.

Regarding the interpretive "wherein" clause recited in claim 30 ("wherein an increase in the amount of HRF protein in the sample from the subject as compared to the amount of HRF protein in the control, (1) indicates endometriosis or a disease caused by endometriosis … or (2) correlates with risk for endometriosis…"), the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results of those steps. Therefore, the "wherein" clause is not considered to further limit the method defined by the claim and has not been given weight in construing the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A 'whereby / wherein' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

Accordingly, it is deemed that Hochstrasser et al. inherently anticipates the claimed invention.

Response to Arguments

8. Applicant's arguments filed May 6, 2010 have been fully considered but they are not persuasive.

A) Applicant argues that Hochstrasser is directed to a method of detecting a cancerous condition, rather than endometriosis as claimed using a correlation that provides an increase in the level of the HRF protein (consonant to TCTPp21) in comparison to control. Applicant specifically contends that Hochstrasser is silent in teaching the correlation between the HRF protein and endometriosis.

In response, Applicant's maintenance of the interpretive "wherein" clause recited in claim 30 ("wherein an increase in the amount of HRF protein in the sample from the subject as compared to the amount of HRF protein in the control, (1) indicates endometriosis or a disease caused by endometriosis … or (2) correlates with risk for endometriosis…"), does not recite any additional active method steps, but simply states a characterization or conclusion of the results of those steps. Therefore, the "wherein" clause is not considered to further limit the method defined by the claim and has not been given weight in construing the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A 'whereby / wherein' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v.

National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

Accordingly, the rejection is being maintained for reasons of record.

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is

(571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

July 12, 2010